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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,705	07/17/2003	Masato Nakada	58647-164	9313
7590	02/14/2006		EXAMINER	
McDERMOTT, WILL & EMERY 600 13th Street, N.W. Washington, DC 20005-3096			NGUYEN, HUONG Q	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/620,705		NAKADA, MASATO	
	Examiner		Art Unit	
	Helen Nguyen		3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7 and 13 is/are rejected.
- 7) ☒ Claim(s) 4-6, 8-12 and 14-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/17/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/17/03, 11/10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10620705, filed on 09/30/2003.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 7/17/2003 and 11/10/2003 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Examiner also notes that the Derwent file submitted on 11/10/2003 by Applicant is not a proper IDS and therefore, unless the references have been cited either on the IDS or Examiner's PTO-892, they have not been considered.

Specification

3. The abstract of the disclosure is objected to because it is lengthy and appears to exceed the maximum length of 150 words. Correction is required. See MPEP § 608.01(b).
4. The disclosure is objected to because of the following informalities: Applicant discloses "extracellular fluid change computing means (23)" on p.22 line 25-26 of the specification. Applicant also previously discloses "extracellular fluid computing means (23)" and "extracellular fluid change computing means (26)." Therefore, it is not clear which of the two is referred to by "extracellular fluid change computing means (23)."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claim 4** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Regarding **Claim 4**, the phrase "for example" or "i.e." (line 9) renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Cherry et al (US Pat No. 5701894). Cherry et al disclose a physiological measuring equipment comprising of a myoelectric change acquiring means (76), an extracellular fluid change acquiring means (80), and a muscle fatigue status determining means (10). Specifically, Cherry et al disclose an EMG sensor (76) that detects a myoelectric change or change in muscle activity (Col.16, line 23-35) and a temperature sensor (80) that detects body temperature (Col.10, line 14-19), wherein body temperature includes extracellular fluid temperature and wherein extracellular fluid temperature

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is considered a type of extracellular fluid change. Cherry et al also disclose a microprocessor module (10) to receive the signals from both the myoelectric change acquiring means (76) and the extracellular fluid change acquiring means (80), as defined above and shown in Figure 2 (Col.15, line 1-7). Because the processor module (10) receives (at least) the two aforementioned signals, it would be obvious for the processor to combine the two in analysis calculations to determine a value such as that for muscle fatigue status, as such computation from multiple signals is within the capabilities of any properly functioning processor (Col.5, line 62-64). Therefore, the microprocessor module (10) is considered a muscle fatigue status determining means capable of determining muscle fatigue status from a myoelectric change and an extracellular fluid change as acquired by the respective means. It is also noted that the elements disclosed by Cherry et al meet all the structural limitations claimed by Applicant, as is sufficient for the rejection of any apparatus claim.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 1, 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherry et al in view of Fukuda et al (US Pub No. 2001/0007055). In regards to **Claim 1**, Cherry et al disclose a myoelectric change acquiring means (76) and a muscle fatigue status determining means (10), both previously explained in the 102(b) rejection of Claim 1. Cherry et al also

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disclose the physiological measuring device comprising of a myoelectric change acquiring means and a muscle fatigue status determining means capable of functioning with other incorporated sensors (Col.15, line 25-28). However, Cherry et al do not disclose an extracellular fluid change acquiring means in the form of impedance.

12. Fukuda et al disclose a muscle fatigue determining device by measuring bioelectrical impedance through electrodes (19, 20), wherein impedance is typically represented by extracellular fluid resistance, thus meriting the consideration of the device as an extracellular fluid change acquiring means (§0057). Because bioelectrical impedance is considered another kind of physiological parameter, it would have been obvious to one skilled in the art at the time the invention was made to modify the physiological measuring system of Cherry et al to include an extracellular fluid change acquiring means (19, 20) using impedance, as taught by Fukuda et al, as such incorporation follows naturally from the scope of invention by Cherry et al, to produce a more complete and improved physiological monitoring device.

13. As stated before, because the processor module (10) of Cherry et al already receives at least two signals during operation (Figure 2), it would be obvious for the processor to combine the signals from the myoelectric change acquiring means (76) along with signals from the extracellular fluid change acquiring means (19, 20) of Fukuda et al, in analysis calculations to determine a value such as that for muscle fatigue status, as such computation from multiple signals is within the capabilities of any properly functioning processor (Col.5, line 62-64 Cherry et al). Therefore, the microprocessor module (10) is considered a muscle fatigue status determining means capable of determining muscle fatigue status from a myoelectric change and

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an extracellular fluid change as acquired by the respective means. It is noted that the above rejection is not meant to undermine the previous 102(b) rejection of the same claim.

14. In regards to **Claim 13**, Fukuda et al disclose the extracellular fluid as an interstitial fluid, wherein interstitial fluid is one component of extracellular fluid (§0060).

15. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cherry et al in view of Fukuda et al, further in view of Ishigooka et al (US Pub No. 2001/0020138). Cherry et al is disclosed above. Fukuda et al disclose an extracellular fluid but do not disclose the extracellular fluid as a ratio of an extracellular fluid to intracellular and extracellular fluid. However, Fukuda et al do disclose the calculation of a ratio of intracellular to extracellular fluid as a measure of human condition such as muscle fatigue (§0142).

16. Ishigooka et al disclose an apparatus for the measure of human condition (edema) also based upon impedance, using either the ratio of intracellular to extracellular fluid, or the ratio of extracellular fluid to total body water (§0010), wherein total body water is defined as the sum of extracellular and intracellular fluid (§0069). Therefore, it would have been obvious to one in the art at the time the invention was made to determine a human condition, such as muscle fatigue with Cherry et al as modified by Fukuda et al, by calculating the ratio of extracellular to intracellular and extracellular fluid (total body water), as defined by Ishigooka, in lieu of using the ratio of intracellular to extracellular fluid, as taught by Fukuda et al, because the two methods both provide an equally effective way to measure human.

Allowable Subject Matter

17. **Claims 2-6, 8-12, 14-18** are objected to as being dependent upon a rejected base claim (**Claim 1**), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. **Claim 4** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kadefors et al (US Pat No. 5645073), Prass (US Pat No. 6181961), Richardson et al (US Pat No. 6185451), and Viertio-Oja et al (US Pub No. 2004/0082876) disclose devices utilizing EMG measurements. Oguma et al (US Pat No. 6472888) discloses an impedance measuring device. Arai et al (US Pub No. 20020156392) discloses a system for inspecting biological rhythms. Konno (US Pat No. 4667513) discloses an apparatus for detection of muscle fatigue.

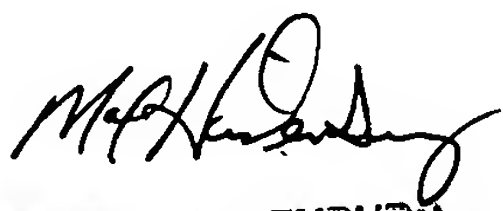
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HQN
2/8/06


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